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100

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/139,058	08/24/98	WOODLE	M 5325-0122.20

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EXAMINER

KISHORE, G

ART UNIT	PAPER NUMBER
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1615

DATE MAILED:

11
12/06/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/139,058

Applicant(s)

Woodle

Examiner

Gollamudi Kishore, Ph.D

Group Art Unit

1615



☒ Responsive to communication(s) filed on Oct 21, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 8, 9, and 11-19 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 8, 9, and 11-19 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

The request for the extension of time, filing of a CPA, amendment and the terminal disclaimer dated 10-21-99 are acknowledged.

Claims included in the prosecution are 8-9 and 11-19.

Claim Rejections - 35 U.S.C. § 112

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:**

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 2. Claims 8-9 and 11-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

‘including in independent claims is indefinite; this term would allow one to interpret that the polymer derivatized lipid is a vesicle forming lipid and according to applicant’s response on page 6 this lipid alone will not form vesicles.

Claim Rejections - 35 U.S.C. § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. Claims 8-9 and 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Janoff ((4,897,384) or Popescu (4,981,692) in view of Yoshioka (5,593,622).

Janoff teaches gentamycin containing liposomes (note the abstract, examples and claims). Janoff however, does not teach that the phospholipids used in the formation of liposomes be attached with the hydrophilic polymer such as polyethylene glycol (PEG).

As pointed out above, Popescu teaches liposome formulations containing gentamycin. Popescu although teaches that cholesterol-PEG could be used in the liposomes, does not teach that phospholipids used in the formation of liposomes be attached with the hydrophilic polymer, polyethylene glycol (PEG).

Yoshioka teaches that when phospholipids which are attached to PEG are used in the formation of liposomes, the hydrophilic moiety of PEG prevents the adsorption of plasma proteins on the liposomes and the subsequent agglutination of liposomes (note the abstract). In essence Yoshioka indirectly teaches that the stability of the liposomes is increased.

The attachment of PEG to the surface of the liposomes (by coupling with the phospholipid) taught by Janoff or Popescu would have been obvious to one of ordinary skill in the art because PEG prevents the adsorption of plasma proteins on the liposomes and the subsequent agglutination of liposomes as taught by Yoshioka.

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Applicants' arguments have been fully considered, but are not found to be persuasive. Applicants argue that the important feature of the Janoff preparation appears to be the ability of the selected ligand to competitively bind with the toxicity receptor and that the modification of the phospholipid head group with a PEG chain will prevent such a binding. This argument is not found to be persuasive since Janoff on columns 15-17 teaches liposomes containing PEG-cholesterol also and according to Janoff even these preparations have reduced toxicity (note col. 17).

Applicants' arguments that Popescu is concerned with RES are not found to be persuasive. These have been addressed before. As pointed out before, on columns 4 and 5 Popescu only refers to the sites the bacteria is likely to infect. On column 5, Popescu teaches the same listeria which is listed in instant specification as one of the bacteria treatable by instant composition (page 42). Since the bacteria are the same the sites of the infection are the same.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

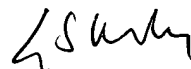
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

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Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

December 3, 1999